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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Lester Hayes,

14 Plaintiff,

15 v.

16 **Wright Medical Technology, Inc., a**
17 **Delaware corporation,**

18 Defendant.

CASE NO. 3:16-cv-01072-CAB-WVG

Judge: Hon. Cathy Ann Bencivengo
Dept.: Courtroom F

Plaintiff's Opposition to Defendant's
Motion for Partial Dismissal

1 Plaintiff Lester Hayes respectfully submits his opposition to defendant
 2 Wright Medical Technology, Inc.'s motion for dismissal of plaintiff's first, fifth,
 3 sixth, seventh, and eight causes of action and plaintiff's prayer for exemplary
 4 damages. Plaintiff does not oppose dismissal of his fifth cause of action for breach
 5 of implied warranty but opposes the balance of defendant's motion.

6 **INTRODUCTION**

7 Wright's motion should, with one exception, be denied. Mr. Hayes's
 8 complaint contains sufficient factual allegations to support his first cause of
 9 action for strict product liability based on manufacturing defect. His complaint
 10 also has specific factual allegations that surmount the particularity requirement
 11 of Federal Rule of Civil Procedure 9(b), so his fraud-related claims—his sixth
 12 cause of action for fraudulent misrepresentation and his seventh cause of action
 13 for fraudulent concealment—defeat dismissal. Mr. Hayes's eighth cause of action
 14 for negligent misrepresentation is not "sounded" in fraud and therefore should
 15 be evaluated under the more permissive Rule 8 standard. *See Petersen v. Allstate*
 16 *Indem. Co.*, 281 F.R.D. 413, 418 (C.D. Cal. 2012). But even if the allegations
 17 supporting negligent misrepresentation are evaluated under Rule 9(b), Mr.
 18 Hayes has adequately pled specific facts to support his negligent
 19 misrepresentation claim. Because plaintiff's fraud-related claims survive,
 20 plaintiff's prayer for exemplary damages should stand, as California law
 21 expressly authorizes exemplary damages in such cases.

22 **FACTUAL BACKGROUND**

23 Plaintiff Lester Hayes underwent a total hip arthroplasty on his left hip on
 24 December 11, 2007. Defendant Wright manufactured the Profemur modular neck
 25 involved in that hip implant surgery. On June 3, 2015, while he was putting on his
 26 shoes, Mr. Hayes's hip device suddenly broke into pieces and he had to be rushed
 27 to the emergency room. The failed device was removed the following day in a
 28 painful surgical procedure commonly referred to as a "revision."

ARGUMENT

1. Standard of review

When ruling on a motion to dismiss, a court must accept as true all material allegations in the challenged pleading, as well as all reasonable inferences that can be drawn therefrom. *Pareto v. FDIC*, 139 F.3d 696, 699 (9th Cir. 1998). The complaint must be read in the light most favorable to the nonmoving party, and dismissal is proper only if there is “a ‘lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory.’” *Conservation Force v. Salazar*, 646 F.3d 1240, 1242 (9th Cir. 2011) (quoting *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir.1988)).

2. Plaintiff's first cause of action for strict products liability is adequately pled

Because Mr. Hayes has specifically pled how the particular device he received deviated from defendant's intended design, the motion to dismiss the cause of action for strict products liability based on manufacturing defect must be denied. "A manufacturing defect exists when an item is produced in a substandard condition." *McCabe v. Am. Honda Motor Co.*, 100 Cal. App. 4th 1111, 1120 (2002). To adequately plead a manufacturing defect claim, plaintiff must state how the product in question deviated from the manufacturer's intended result. Wright Motion for Partial Dismissal, pp. 3-4, ECF Docket No. 9; *Lucas v. City of Vasilia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010) (plaintiff must allege "how the [product] either deviated from [the manufacturer's] intended result/design or how the [product] deviated from other seemingly identical models); *Barker v. Lill Engineering Co.*, 20 Cal.3d 413, 429 (1978).

Mr. Hayes has done that here. In his complaint, he alleged that his device deviated from defendant's intended design or result, or other seemingly identical products by having "an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the

1 modular neck and catastrophic failure of the device, requiring revision surgery.”
 2 Complaint, ¶ 89, ECF Doc. No. 1. This is a clear statement of *how* the device in
 3 question differed because it was defectively manufactured. *See Lucas, supra*, 726
 4 F. Supp. 2d 1149, 1155. That a few other paragraphs in plaintiff’s complaint
 5 discussed the product’s design does not erase the factual allegations pertaining
 6 to plaintiff’s manufacturing defect claim.

7 **3. Plaintiff’s sixth, seventh, and eighth causes of action are pled with**
 8 **sufficient particularity**

9 Defendant primarily challenges plaintiff’s fraud-related claims, arguing
 10 they do not meet the heightened pleading requirements imposed by Rule 9(b).
 11 This is not true. Plaintiff’s complaint provides ample factual basis as judged
 12 under Rule 9(b) for his fraud claims (his sixth and seventh causes of action), as
 13 well as for his eighth cause of action for negligent misrepresentation, though that
 14 claim should be judged under the more permissive Rule 8 standard. Because
 15 plaintiff’s complaint contains factual allegations that satisfy the requirements
 16 under Rule 9(b), defendant’s motion to dismiss should be denied as to plaintiff’s
 17 sixth, seventh, and eighth causes of action.

18 **A. Rule 9(b) particularity**

19 A pleading is sufficient under Rule 9(b) if it “[identifies] the circumstances
 20 constituting fraud so that the defendant can prepare an adequate answer from
 21 the allegations.” *Walling v. Beverly Enters.*, 476 F.2d 393, 397 (9th Cir. 1973).
 22 Ordinarily, this requires the plaintiff to “identify the ‘who, what, when, where and
 23 how of the misconduct charged,’ as well as ‘what is false or misleading about [the
 24 purportedly fraudulent conduct]’, and why it is false.” *Cafasso, ex rel. United*
 25 *States v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting
 26 *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)).

27 While fraud claims are generally held to a higher standard under Rule 9(b),
 28 the level of specificity required depends on the nature of the claim. When a claim

1 primarily relies on “acts” of omission, the level of specificity required is relaxed.
 2 *Falk v. General Motors Corp.*, 496 F. Supp. 2d 1088, 1099 (N.D. Cal. 2007) (“[A]
 3 fraud by omission claim can succeed without the same level of specificity
 4 required by a normal fraud claim.”)

5 **B. Plaintiff's causes of action for fraudulent misrepresentation and
 6 fraudulent concealment are pled with sufficient particularity**

7 Mr. Hayes's complaint contains sufficient factual details about Wright's
 8 fraudulent misrepresentation and concealment to defeat Defendant's motion.
 9 The elements of fraudulent misrepresentation are: (1) misrepresentation; (2)
 10 knowledge of falsity; (3) intent to defraud or to induce reliance; (4) justifiable
 11 reliance; and (5) resulting damage. *Engalla v. Permanente Med. Grp., Inc.*, 15
 12 Cal.4th 951, 974 (1997). A plaintiff must “establish a complete causal
 13 relationship between the alleged misrepresentations and the harm claimed to
 14 have resulted” to adequately plead reliance (*Mirkin v. Wasserman*, 5 Cal.4th 1082,
 15 1092 (1993)), and actual reliance exists when it appears, to a reasonable
 16 probability, the plaintiff would not have entered the transaction absent the
 17 representation. *Cadlo v. Owens-Illinois, Inc.*, 125 Cal. App. 4th 513, 519 (2004).

18 The elements for fraudulent concealment are logically similar to those for
 19 fraudulent misrepresentation: (1) the defendant concealed a material fact; (2)
 20 the defendant had a duty to disclose the fact to plaintiff; (3) the defendant
 21 intentionally concealed the fact with the intent to defraud; (4) the plaintiff must
 22 have been unaware of the fact and would have acted differently had he known
 23 the fact; and (5) resulting damages. *Boschma v. Home Loan Center, Inc.*, 198
 24 Cal.App.4th 230, 248 (2011).

25 Defendant takes issue with the level of specificity with which those
 26 elements are pled, in particular reliance, choosing certain excerpts to paint a
 27 picture of a very conclusory complaint. But defendant cannot pick and choose
 28 which allegations in the complaint to give credence to, and plaintiff's complaint

1 contains a number of specific allegations that support his claims for fraudulent
 2 misrepresentation and concealment. For example, paragraph 20 of the complaint,
 3 one of the paragraphs containing phrases challenged by defendant, actually
 4 includes a number of specific details as to the "who, what, when" of the alleged
 5 fraud:

6 In various marketing and promotional material published and
 7 distributed by Wright from approximately the year 2002, and into
 8 the year 2005, and available to Wright's sales representatives and
 9 distributors, surgeons, patients, and the general public, Wright
 10 made the following representations, statements, claims, and
 11 guarantees about its Profemur modular necks:

12 The modular neck used with the Profemur Hip has been
 13 employed by Wright Cremascoli for over 15 years. The necks
 14 were designed in 1985 and have been successfully implanted
 15 in over 50,000 patients requiring both primary and revision
 16 hip procedures. The necks are used in other Wright Cremascoli
 17 hip systems besides the Profemur Hip. None of the necks has
experienced a clinical failure since their inception.

18 and,

19 The modular neck system, designed by Cremascoli in 1985
 20 (U.S. Patent #4,957,510), has now been successfully implanted
 21 in over 50,000 patients requiring both primary and revision
 22 hip arthroplasty. Extensive laboratory tests have proven that
 23 the coupling between the modular neck and femoral implant
 24 guarantees:

- 18 • Structural reliability
- 19 • Absence of significant micromovement
- 20 • Absence of fretting corrosion

21 [Wright Medical Technical Monograph MH688-102 ©2004]

22 This particular paragraph provides a copyright citation to one specific source of
 23 alleged material misrepresentations and highlights the particularly fraudulent
 24 portions. Plaintiff could hardly plead a misrepresentation with more specificity.

25 Looking at the elements more broadly, Plaintiff has adequately pled all
 26 elements of his sixth and seventh causes of action. Plaintiff alleges Wright failed
 27 to inform its Profemur patients of certain risks by omitting specific material facts,
 28 including: (1) the higher than anticipated rate of failure of the device; (2) reports
 of fractures of other implanted Profemur devices; (3) that failures of Profemur

1 are known to be associated with higher impact activities and heavier patients;
 2 and that failures of Profemur are known to be associated with normal daily
 3 activities. Complaint, ¶¶ 36-45, 66, ECF Doc. No. 1. Wright made affirmative
 4 misrepresentations about and/or concealed these specific facts about the
 5 Profemur modular neck despite its knowledge to the contrary. Complaint, ¶¶ 50-
 6 54. Further, "Plaintiff and Plaintiff's healthcare providers relied upon Defendants'
 7 incomplete and inaccurate representations as to the safety and performance of
 8 the [Profemur] when selecting, recommending, and implanting the [Profemur]"
 9 and "Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of
 10 said representations and reasonably believed them to be true." Complaint, ¶¶
 11 125, 141. Put another way, but for Wright's misrepresentation and/or
 12 concealment, plaintiff and his doctors would not have selected the Profemur
 13 modular neck. Plaintiff has adequately pled all elements of his fraud claims,
 14 including reliance, by showing a causal connection between the alleged fraud and
 15 harm suffered. *See Mirkin, supra*, 5 Cal.4th at 1092.

16 Plaintiff's complaint contains a number of specific factual allegations
 17 relating to fraud, answering the key questions as required under Rule 9(b). See
 18 *Cafasso, supra*, 637 F.3d 1047, 1055. Because plaintiff has pled with sufficient
 19 particularity all elements of fraudulent misrepresentation and fraudulent
 20 concealment, defendant's motion to dismiss should be denied as to plaintiff's
 21 sixth and seventh causes of action.

22 **C. Plaintiff's eighth cause of action for negligent misrepresentation is
 23 not sounded in fraud and should be evaluated under Rule 8**

24 Rule 9(b) applies not only where fraud is an essential element of a claim,
 25 but also where the claim is "sounded" or "grounded" in fraud. *Vess v. Ciba-Geigy*
 26 *Corp., U.S.A.*, 317 F.3d 1097, 1103-1104 (9th Cir. 2003). A claim is considered
 27 "grounded" or sounded in fraud where plaintiff alleges defendant engaged in
 28 fraudulent conduct and relies solely on that conduct to prove that claim. *Ibid.* The

1 Ninth Circuit has not yet opined on whether negligent misrepresentation claims
 2 must be evaluated under Rule 9(b)'s heightened requirements, and there is
 3 disagreement among the district courts. *See e.g., Green v. Cent. Mortgage Co.*, 148
 4 F. Supp. 3d 852 (N.D. Cal. 2015) (Rule 9(b) applies to negligent
 5 misrepresentation claims); *Petersen v. Allstate Indem. Co.*, 281 F.R.D. 413, 418
 6 (C.D. Cal. 2012) ("[B]ecause an allegation of negligent misrepresentation suggests
 7 only that the defendant failed to use reasonable care—an objective standard—it
 8 does not result in the kind of 'harm' that Rule 9(b) was designed to prevent.").

9 The reasoning in *Petersen* is sound. Plaintiff's negligent misrepresentation
 10 cause of action asserts Wright breached its duty to truthfully represent its
 11 product to the medical duty, the public, and plaintiff according to an objectively
 12 reasonable standard. Plaintiff's negligent misrepresentation cause of action
 13 should be evaluated under Rule 8.

14 **D. Regardless of whether Rule 8 or Rule 9(b) provides the standard,
 15 plaintiff has sufficiently pled his negligent misrepresentation claim**

16 Whether Rule 8 or Rule 9(b) provides the standard against which plaintiff's
 17 allegations supporting his negligent misrepresentation claim must be judged, the
 18 complaint contains more than sufficient specific factual allegations to defeat
 19 defendant's motion to dismiss. Negligent misrepresentation has essentially the
 20 same elements as fraudulent misrepresentation, except a plaintiff need not show
 21 the defendant knew of the falsity of the statement, but rather that the defendant
 22 lacked any reasonable grounds for believing the statement to be true. *Charney v.*
 23 *Cobert*, 145 Cal.App.4th 170, 184 (2006). As discussed more fully above,
 24 plaintiff's complaint contains specific factual allegations sufficient to meet Rule
 25 9(b)'s heightened pleading standard as to plaintiff's claim for fraudulent
 26 misrepresentation. *See* Complaint, ¶¶ 20, 36-45, 66, 125, ECF Doc. No. 1. Because
 27 plaintiff has sufficient factual allegations supporting a claim evaluated under the
 28 higher standard of Rule 9(b), plaintiff's factually similar claim for negligent

1 misrepresentation must also defeat dismissal regardless of which standard it is
 2 evaluated under.

3 **E. Defendant's "fraud on the FDA" argument is irrelevant**

4 Wright offers an additional basis for dismissing plaintiff's sixth through
 5 eighth causes of action, arguing plaintiff in effect alleges fraud on the FDA. Wright
 6 Partial Motion to Dismiss, pp. 14-15, ECF Doc. No. 9. According to defendant,
 7 plaintiff is trying to assert an impermissible claim for fraud on the agency
 8 couched within his fraud-related causes of action. Relying largely on *Buckman Co.*
 9 *v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001), Wright claims "Plaintiff's fraud-
 10 based claims must be dismissed because they are preempted by federal law."
 11 Wright Motion, p. 15, ECF Doc. No. 9.

12 In reality, the complaint as written does not allege fraud on the FDA, but
 13 rather fraud on plaintiff, fraud on his physicians, and fraud on the medical
 14 community. Allegations related to Wright misleading the FDA serve to illustrate
 15 the depths of Wright's false, deceptive, and fraudulent marketing. Nothing in the
 16 *Buckman* case precludes plaintiff from doing so. Were defendant's reading to
 17 hold, plaintiff's claims would be defeated because they mentioned the FDA, even
 18 if the claims were otherwise legally sound. In fact, later decisions have rejected
 19 the same argument Wright now asserts. See e.g., *Globetti v. Sandoz Pharm. Corp.*
 20 No. 98-2649, 2001 U.S. Dist. LEXIS 2391, *8 (N.D. Ala. Mar. 5, 2001) ("[w]hile
 21 plaintiff may not offer evidence simply to show misrepresentations to or
 22 concealment from the FDA, such evidence may be relevant to showing the
 23 defendant's knowledge relating to the adequacy of the warning or the truth of
 24 information represented to or concealed from plaintiff or her physician.");
 25 *Bouchard v. American Home Products Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio
 26 2002) (If [plaintiff's] claims are based on direct fraud against her and her
 27 healthcare provider, rather than the FDA, then her claims are not preempted, and
 28 evidence concerning what information was and was not provided to the FDA

1 might still be relevant.”).

2 Defendant’s preemption argument is misplaced. Plaintiff’s allegations are
 3 not premised upon a “fraud on the FDA” and, therefore, are not preempted by
 4 federal law.

5 **4. Plaintiff’s prayer for punitive damages must survive as plaintiff’s
 6 fraud claims defeat dismissal**

7 As correctly explained by defendant, because this case is before the court
 8 based on diversity jurisdiction, California law governs plaintiff’s prayer for
 9 exemplary damages, and California law specifically authorizes such damages
 10 where there is “oppression, *fraud*, or malice.” Cal. Civ. Code § 3294 (italics
 11 added); *see e.g.*, *Gelow v. Cent. Pac. Mortgage Corp.*, 656 F. Supp. 2d 1217, 1234
 12 (E.D. Cal. 2009) (Under California law, “[t]here is no bar to awarding punitive
 13 damages for fraud when the underlying tort is fraud.”); *Miller v. Nat'l Am. Life Ins. Co.*, 54 Cal. App. 3d 331, 336, 126 Cal. Rptr. 731, 733 (Ct. App. 1976) (“[P]roof of
 14 the cause of action for fraud is itself an adequate basis for awarding punitive
 15 damages.”)

16 As explained above, plaintiff has adequately pled his fraud-related claims.
 17 Defendant’s reference to “clear and convincing evidence” is inapposite at the
 18 pleading stage, as plaintiff has sufficiently alleged fraud. Defendant’s lengthy
 19 explanations pertaining to malice and oppression are similarly extraneous. *See e.g.*,
 20 *Glovatorium, Inc. v. NCR Corp.*, 684 F.2d 658, 663 (9th Cir. 1982) (“There is no
 21 requirement under Cal. Civil Code § 3294 that malice, reprehensible or
 22 outrageous conduct or willful disregard be shown in addition to the fraud.”).
 23 Because of this, plaintiff’s prayer for exemplary damages should stand.

CONCLUSION

Wright's partial motion to dismiss should be denied based on the foregoing, with the exception of plaintiff's conceded fifth cause of action for breach of implied warranty.

Dated: July 7, 2016

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JUDGE: Hon. Cathy Ann Bencivengo

Hayes v. Wright Medical Technology, Inc., et al.
U.S.D.C. Southern District of California Case No. 16-CV-1072-CAB-WVC

I, the undersigned, declare: That I am, and was at the time of service of the papers herein referred to, over the age of eighteen years, and not a party to the action; and I am employed in the County of San Diego, California. My business address is 110 Laurel Street, San Diego, California 92101.

On July 7, 2016, at San Diego, California, I served the following document(s) described as **PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR PARTIAL DISMISSAL** on the parties in said action as follows:

- ELECTRONIC TRANSMISSION:** I filed the foregoing document with the Clerk of Court for the U.S.D.C. Southern District of California, using the Electronic Case Filing ("ECF") system of the Court. The attorney listed above has consented to receive service by electronic means and is registered with the Court's ECF system and was served a "Notice of Electronic Filing" sent by ECF system.
- FEDERAL COURT:** I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on July 7, 2016, at San Diego, California.

/s/ Maggie Strohlein